

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**REPLY IN SUPPORT OF MOTION TO EXCLUDE
GENERAL-CAUSATION TESTIMONY OF ROBERT D. MOORE, D.O.**

Plaintiffs attempt to transform the methodologically flawed opinions Ethicon challenges here into those based on sound scientific methodology simply because Dr. Moore may be qualified to give expert testimony. Ethicon did not base its *Daubert* challenge on qualifications. Thus, Plaintiffs' lengthy recitation of Dr. Moore's qualifications (Pls.' Resp. (Dkt. 2204) at 1-3) is both unnecessary and immaterial. No matter how qualified Dr. Moore may be to give opinions in this case, "he must still base his opinions on a reliable, scientific method." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 680 (S.D.W. Va. 2014).

Some of the opinions challenged here are not based on a reliable, scientific method; others are irrelevant, unhelpful, or misleading under Rules 702, 703, and 403, and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Plaintiffs' arguments in opposition do not cure these deficiencies. More specifically, Plaintiffs:

- ignore Dr. Moore's failure to control and account for overinclusiveness in the study he conducted where he grouped, without distinction, multiple products, multiple surgical techniques, and multiple complications, yet he opined that the TVT-O alone causes the complications observed in the study;

- fail to acknowledge that relying on medical literature alone does not demonstrate that Dr. Moore’s opinions are the result of a reliable methodology if Dr. Moore effectively rewrites that literature to say something the literature does not say, including
 - transforming “may cause” contained in certain literature into “have caused” based merely on his *ipse dixit* that an author’s use of terms expressed in possibility—i.e., “may” and “perhaps” are “verbiage” required by medical journal editorial staff and not what the authors really meant; and
 - completely changing the authors’ conclusions into what Dr. Moore thinks the authors should have concluded;
- fail to recognize that Dr. Moore’s dismissiveness of a contrary study because it is only “one study” is unlike the case law they rely;
- are unable to controvert the cases throughout the country, including the Fourth Circuit, holding that evidence of alternative surgical techniques is irrelevant to claims for design defect;
- continue to assert that Dr. Moore can testify that the TVT-O is “dangerous” and that its warnings are “inadequate” despite Plaintiffs’ recognition that an expert is prohibited from offering legal conclusions;
- fail to recognize that Dr. Moore’s reliance on internal company documents is not for the permissible purpose of providing bases for his IFU opinions but to impermissibly show what Ethicon “knew”;
- do not distinguish Dr. Moore’s opinions concerning the competency of other physicians from essentially identical opinions the Court has previously excluded as irrelevant under the same record and arguments; and
- offer no argument in opposition as to Dr. Moore’s opinions about Ethicon’s marketing practices, what other physicians know, or that a diagram should have been included in the IFU; they therefore effectively concede that these opinions fail to pass muster under *Daubert*.

Accordingly, as explained more fully below, Ethicon respectfully asks that the Court exclude the opinions of Dr. Moore as set forth in its Memorandum. *See* Defs.’ Mem. (Dkt. 2120).

ARGUMENTS AND AUTHORITIES

I. Plaintiffs fail to acknowledge that the study conducted by Dr. Moore did not control for differences among the many products involved so that the study would serve as a reliable basis to opine that the TVT-O, and only the TVT-O, caused complications observed.

This Court has repeatedly found that an expert's own study that failed to account or control for error or bias is not reliable and is not a valid basis for that expert's general-causation opinions. *See Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D.W. Va. Jan. 15, 2014); *see also Eghnayem*, 57 F. Supp. 3d at 687; *Hall v. Boston Scientific Corp.*, No. 2:12-cv-08186, 2015 WL 868907, at *25 (S.D.W. Va. Feb. 27, 2015). Plaintiffs make no attempt to distinguish this case law or address it in any way.

Instead, they argue that because Dr. Moore's study is "the largest known stud[y] of mesh complications" and because it is published in a peer-reviewed journal, it is a reliable basis for Dr. Moore's opinion that the TVT-O causes the complications observed in the study. Pls.' Resp. (Dkt. 2204) at 3-4. It may be the "largest known study," however, because, as Dr. Moore readily admitted, it involved many other products besides the TVT-O and provided no breakdown of complications by product or procedures. *See* Defs.' Mem. (Dkt. 2120) at 3-4. Instead, *all* explanted transvaginal mesh products regardless of the type of mesh product, surgical approach, or manufacturer were grouped together. *Id.*; *see also* Ex. E to Defs.' Mot. (Dkt. 2119-5), *The IUGA-ICS Classification* article; Ex. D to Defs.' Mot. (Dkt. 2119-4), Moore 4/15/16 Dep. Tr. 57:20-58:17, 59:7-60:11.

Thus, Ethicon does not take issue with Dr. Moore's study because it "was not solely limited to the TVT-O," as Plaintiffs contend. *See* Pls.' Resp. (Dkt. 2204) at 4. Dr. Moore can include as many different products and procedures in his study as he wanted to study. But to be a reliable basis for his opinion that the TVT-O causes the complications he observed, he must have

accounted for complications *by product* and *procedure* to draw any reliably reached conclusions. He did not. And because he did not, his overinclusive results are a faulty premise for his opinion that the TVT-O and only the TVT-O caused the complications he observed. Additionally, to allow the jury to hear results of Dr. Moore's study uncorrected and uncontrolled for product type and procedure would be misleading and unfair, and thus unduly prejudicial under Rule 403.

II. Dr. Moore cannot rewrite medical literature to say what he wants it to say or disregard contrary literature without explanation.

Ethicon readily acknowledged that an expert's reliance on medical literature is an acceptable methodology for an expert to form general-causation opinions. Defs.' Mem. (Dkt. 2120) at 7-8. But the literature relied upon must actually support the author's opinions. *Id.* Dr. Moore cannot rewrite that literature to say what he wants or dismiss contrary literature without explanation.

A. Dr. Moore rewrites literature that says "may cause" a certain complication to "have caused" that complication.

Plaintiffs confuse the degree of proof required to prove causation with terms used by a scientist when reporting results of a peer-reviewed study. Ethicon does not contend that a scientist is required to report results in a peer-reviewed journal "to a reasonable degree of scientific certainty," as Plaintiffs claim. Pls.' Resp. (Dkt. 2204) at 6. That is not the law, nor did Ethicon claim it to be. What the scientist and the journal decide to publish are governed by different standards than what a court decides should be admissible evidence.

Consistent with well-established case law, words of *possibility* are not words of *probability*. *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 681 (M.D.N.C. 2003). Indeed, a conclusion expressed in terms of possibility is merely an untested hypothesis, "not admissible scientific 'knowledge,'" nor is it "'based on sufficient facts or data' or the 'product of reliable principles and methods . . . applied . . . reliably to the facts of the case.'" *Tamraz v. Lincoln Elec.*

Co., 620 F.3d 665, 670 (6th Cir. 2010) (quoting Rule 702); *see also id.* at 677 (“The issue is the reliability of [the expert’s] opinion from a *legal* perspective. And what science treats as a useful but untested hypothesis the law should generally treat as inadmissible speculation.”) (emphasis *sic*).

Recognizing the speculative nature of “may cause” as those terms are used in the studies he relies upon, Dr. Moore claims those words do not express the authors’ actual intent. Dr. Moore goes so far as to say that “may cause” is mere “verbiage” required by medical journals and what the authors really meant was “have caused.” *See* Defs.’ Mem. (Dkt. 2120) at 6. Unlike Humpty Dumpty,¹ Dr. Moore is not permitted to redefine the definition of a word or rewrite them to say something other than what they actually say.

B. Dr. Moore rewrites the Teo study to give it a conclusion he wants, not a conclusion reached by the authors.

Nowhere in the Teo study do the authors conclude that “it was no longer ethical to use the TVT-O device given the clear negative impact on patient health,” nor did they recommend a retropubic placement. *See* Defs.’ Mem. (Dkt. 2120) at 8-9; *see also* Ex. H to Defs.’ Mot. (Dkt. 2119-8), *Randomized Trial* article. Instead, as Ethicon showed, the authors concluded that both retropubic and transobturator tape procedures have “a high cure rate with low rate of complications.” Defs.’ Mem. (Dkt. 2120) at 9. In fact, Ethicon excerpted the entire conclusion from the Teo study and nowhere in that conclusion do the authors claim that it is unethical to use the TVT-O or that the retropubic placement is recommended over the TVT-O.

For medical literature to be a reliable methodology, Dr. Moore must rely on the literature as it is written. He cannot rewrite that literature for it to say something it does not or “infer[]

¹ “When I use a word,” Humpty Dumpty said, in rather a scornful tone, “it means just what I choose it to mean—neither more nor less.” Lewis Carroll, *Through the Looking Glass* 205 (1872).

conclusions from studies and reports that the papers do not authorize.” *McClain v. Metabolife Int’l Inc.*, 401 F.3d 1233, 1240 (11th Cir. 2005). This is not “wish[ing] away” peer-reviewed literature as Plaintiffs contend (*see* Pls.’ Resp. (Dkt. 2204) at 5), but holding Dr. Moore accountable to the literature he relies upon as that literature is written, not as he wishes it to be.

C. Dr. Moore adds causation conclusions to the statistical analyses contained in the Cochrane database review.

Dr. Moore agrees that the Cochrane database review reported only statistics and did not provide any explanation for cause. Defs.’ Mem. (Dkt. 2120) at 5. Yet he takes an unexplained leap from those statistics to causation merely on his say-so. Pls.’ Resp. (Dkt. 2204) at 6. Like other literature he relies upon and discussed above, Dr. Moore again transforms this literature into something it is not to give his causation opinions the imprimatur of scientific validity.

Putting to the side the lack of a reliable methodology, which cannot be done under Rules 702 and 703, it would be highly prejudicial to Ethicon for Dr. Moore to come into court under the aura of an expert’s credentials and mislead the jury that his general-causation opinions are supported by the scientific literature when that literature does not say what Dr. Moore claims it says. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (recognizing that “expert witnesses have the potential to ‘be both powerful and quite misleading’”) (quoting *Daubert*, 509 U.S. at 595). Like the expert in *McClain*, Dr. Moore should not be permitted to do so. *McClain*, 401 F.3d at 1240.

D. Dismissing a contrary study without a scientific basis for doing so renders Dr. Moore’s literature-review methodology unreliable.

Ethicon did not argue that Dr. Moore failed to account for the Debodinance study as Plaintiffs claim, *see* Pls.’ Resp. (Dkt. 2204) at 10, but rather that Dr. Moore dismissed the Debodinance study because it was just “one study.” Defs.’ Mem. (Dkt. 2120) at 10.

Plaintiffs reliance then on *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202 (S.D.W. Va. Feb. 7, 2015), is misplaced. The expert in that case addressed the contrary study and provided an explanation. *Id.* at *12. That is not what Dr. Moore does here. He dismisses a scientifically valid, peer-reviewed study because it was just “one study,” which is not a valid basis for dismissing a study’s results. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *12-13 (S.D.W. Va. Sept. 29, 2014).

Plaintiffs’ reliance on *Carlson v. Boston Scientific Corp.*, No. 2:13-cv-05475, 2015 WL 1931311 (S.D.W. Va. Apr. 28, 2015), is equally misplaced. There is no argument that Dr. Moore’s methodology is faulty because he relied upon only one study as was the defendant’s argument in *Carlson*. *Id.* at *12. *Carlson* simply does not apply.

III. This Court’s preemption analysis has nothing to do with whether an alternative surgical technique can support a claim for design defect; Plaintiffs’ argument ignores uncontroverted Fourth Circuit precedent.

“It is well established that a medical device manufacturer is not responsible for the practice of medicine.” *Sons v. Medtronic Inc.*, 915 F. Supp. 2d 776, 783 (W.D. La. 2013). “For physician-prescribed drugs and medical devices, the physician ‘is in the best position to understand the patient’s needs and assess the risks and benefits of a particular course of treatment.’” *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163 (4th Cir. 1999).

That a plaintiff’s surgeon could have used an outside-in surgical technique instead of an inside-out technique as Dr. Moore opines here does not demonstrate a design defect in the TVT-O mesh product, as Dr. Moore claims. *See* Ex. C to Defs.’ Mot. (Dkt. 2119-3), Moore Report at 18. The Fourth Circuit Court of Appeals in *Talley* made clear that these assertions “questioned the medical judgment of doctors,” and might be relevant in a malpractice suit against the doctor, but not a suit against the manufacturer. *Id.* at 162. Surgical alternatives “[do] not indicate any design flaw.” *Id.* Indeed courts have rejected Plaintiffs’ surgical-technique design-defect

argument (*see* Defs.’ Mem. (Dkt. 2120) at 9-10), and Plaintiffs cite no case law that supports their erroneous argument (*see* Pls.’ Resp. (Dkt. 2204) at 7-10).

Instead, Plaintiffs claim that Ethicon’s argument is “self-contradictory” and conflicts with *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748 (S.D.W. Va. 2014). Not so. *Lewis* addressed *preemption*—i.e., whether the plaintiff’s design-defect claims were preempted if the Prolene sutures that were part of the TVT mesh device went through the FDA’s premarket approval process. Surgical technique was not discussed, and thus was not at issue, and consequently had no bearing on the *Lewis* court’s analysis or ruling. There is no conflict.

Nor does Ethicon’s argument here “contradict” its argument in *Lewis*. Instead, Ethicon asks the Court to rule consistent with Fourth Circuit and courts around the country that, while Dr. Moore’s alternative-surgical-technique opinions may be relevant to other claims, they are not relevant to design-defect claims in general and cannot support Plaintiffs’ contention that the TVT-O is defective in design. *See Talley*, 179 F.3d at 162 (rejecting plaintiff’s theory that defendant’s spinal-fixation device was defective because there were alternative spinal-fusion procedures available that did not use spinal-fixation devices); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert’s “testimony fails to identify any *particular* defect with the product. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant it with any degree of success, that if he were designing a pedicle screw he would design it differently The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon.”); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and non-instrumental spinal repair, not a defect in

the product itself); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (granting summary judgment to defendant because “[t]he fact that an alternative method of surgical hernia repair was potentially available does not support[] Plaintiff[s] design defect claim”).

Dr. Moore’s surgical-technique design-defect opinion offered runs counter to this established and uncontroverted Fourth Circuit precedent, and therefore is irrelevant to a claim for design defect. *See Daubert*, 509 U.S. at 591-92 (explaining that an expert’s opinion must “fit” the relevant inquiry, and that scientific validity for one purpose is not necessarily scientific validity for other purposes).

IV. An alternative design that is not, nor cannot be, commercially available is not a *feasible* alternative design to support a claim for design defect.

Plaintiffs cite inapposite case law as support for Dr. Moore’s opinion that the Abbrevio mesh product is a safer alternative to the TVT-O. *See* Pls.’ Resp. (Dkt. 2204) at 11-12. Unlike the child-safety seat at issue in *Cardenas v. Dorel Juvenile Grp., Inc.*, 230 F.R.D. 611 (D. Kan. 2005), a prescription medical device cannot be legally sold in the United States without either FDA approval or clearance. Before that time, an alternative prescription product is simply not a “feasible” alternative because it is not legally available.

V. Dr. Moore’s “interpretation” of Ethicon internal documents are offered for the purpose of showing what Ethicon knew, not to explain the basis of his IFU opinions.

Ethicon acknowledges that an expert “may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions.” *Sanchez*, 2014 WL 4851989, at *4. But that is not why Dr. Moore relies on Ethicon’s internal documents here. Dr. Moore intends to “interpret” these documents to show that Ethicon “had information known or available” to it as to the safety and efficacy of the TVT-O that is not set

forth in its warnings. Pls.’ Resp. (Dkt. 2204) at 13. Indeed, Plaintiffs concede Dr. Moore will opine that Ethicon was “aware of other risks.” *Id.*

Plaintiffs try to exempt Dr. Moore’s “corporate knowledge” opinion because they claim it does not go to Ethicon’s “motives or intent” and is not related to “corporate conduct or ethics.” *Id.* at 13-14. But corporate motives, intent, or ethics² are not the only bases of improper testimony by an expert relying on internal company documents. As this Court has repeatedly held, an expert is also prohibited from testifying about what a company “knows” or “knew” based on that expert’s review of company records. *See* Defs.’ Mem. (Dkt. 2120) at 13. The jury is capable of reading and interpreting company documents; it needs no expert testimony to explain what those documents mean. *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *10 (S.D.W. Va. July 8, 2014). Dr. Moore should be precluded from interpreting Ethicon company documents and testifying to what he claims Ethicon “knew.”

VI. Dr. Moore provides no reliable basis that the TVT-O IFU should have included frequency, severity, and duration information.

Plaintiffs make no attempt to distinguish *Wise*, 2015 WL 521202, or *Frankum v. Boston Scientific Corp.*, No. 2:12-cv-000904, 2015 WL 1976952, at *21 (S.D.W. Va. May 1, 2015), cited by Ethicon to show that Dr. Moore’s opinion—*i.e.*, it is a “surgeon’s right” to have frequency, severity, and duration information included in a product IFU—has no reliable basis. *See* Defs.’ Mem. (Dkt. 2120) at 13-14; *see also* Pls.’ Resp. (Dkt. 2204) at 14-15. And Plaintiffs provide no authority for this “right” and fail to show that Dr. Moore’s “surgeon’s right” opinion has any reliable basis. Nowhere in *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL

² Plaintiffs erroneously claim that Dr. Moore is not offering any opinions on corporate ethics. Yet in his report he opines that Ethicon acted contrary to its duty to act as a “responsible medical device manufacturer.” Ex. C to Defs.’ Mot. (Dkt. 2119-3), Moore Report at 37; *see also* Defs.’ Mem. (Dkt. 2120) at 13. This is not a close question. His opinion is not on the periphery of what is inadmissible; it hits the middle of the bull’s eye.

5700513, is this “surgeon’s right” addressed, nor does this case otherwise show that Dr. Moore’s frequency-severity-duration opinion results from a reliable methodology.

VII. Plaintiffs fail to show how Dr. Moore’s physician-competency opinions are relevant.

The Court has already determined that opinions addressing the competence of other surgeons in implanting TVT-O are irrelevant and unhelpful. *Edwards*, 2014 WL 3361923, at *17. Plaintiffs fail to address or distinguish *Edwards*. See Pls.’ Resp. (Dkt. 2204) at 15.

They claim nonetheless that Dr. Moore should be allowed to offer his opinions regarding physician competency and training because physician error is sometimes a defense in this litigation. *Id.* Plaintiffs offer no specific support for this contention but nonetheless claim, without support, that Dr. Moore’s physician-competency opinion is “demonstrably reliable.” *Id.*

To be sure, surgeon error may be relevant to the issue of specific causation in an implantable device case. In contrast, however, general-causation testimony about physician training and competency “says little about the design . . . or the adequacy of [a product’s] warnings.” *Wise*, 2015 WL 521202, at *13. As a result, there is no “valid scientific connection” between physician-competency testimony and the issues present in this litigation. These types of opinions are irrelevant and should be excluded. *Id.*

Because Dr. Moore’s opinions as to physician competency are no different than the same physician-competency opinions already excluded by this Court, Dr. Moore’s similar opinions are also inadmissible. See, e.g., *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *23 (S.D.W. Va. May 6, 2015) (adhering to the Court’s earlier ruling where the expert’s rejected opinions were unchanged from those already addressed).

VIII. Plaintiffs concede Dr. Moore cannot offer legal conclusions but then claim he can.

Despite Plaintiffs' concession that an expert cannot offer legal conclusions, they nonetheless claim that Dr. Moore can testify that the TVT-O is "dangerous" and that Ethicon failed to adequately warn. Pls.' Resp. (Dkt. 2204) at 4. These are legal conclusions that are within the province of the jury, not Dr. Moore. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013) (distinguishing between an expert's permissible opinion under Rule 704 and when that expert instead offers an impermissible legal conclusion); *see also Eghnayem*, 57 F. Supp. 3d at 691.

IX. Plaintiffs point to nothing to show that Dr. Moore's "unacceptable" complication-rate opinion results from a reliable methodology.

Ethicon is not "quibbling" over Dr. Moore's use of the term "unacceptable" as he uses that term to support his opinion that the TVT-O has "unacceptable" complication rates. He is free to use that term to the extent it is supported by a reliable methodology. But it is not. Dr. Moore made no attempt to define what "unacceptable" means in his report (*see* Ex. C to Defs.' Mem. (Dkt. 2120), Moore Report at 41) and Plaintiffs fail to show in their opposition that this opinion rests on a reliable methodology (*see* Pls.' Resp. (Dkt. 2204) at 15-16). Dr. Moore's complication-rate opinion remains subjective, over-general, and unsupported; it amounts to nothing more than his *ipse dixit* or his personal belief. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). As a result, this is not a matter for cross-examination as Plaintiffs contend, but an inadmissible opinion.

X. Plaintiffs do not contest the inadmissibility of Dr. Moore's marketing opinion, what-other-physicians-know opinion, or his opinion that the IFU should have contained a diagram.

Ethicon argued that Dr. Moore should be precluded from offering opinions about Ethicon's marketing practices, what other physicians knew, and that the IFU should have

contained a diagram. Defs.' Mem. (Dkt. 2120) at 14-16. Plaintiffs offer no argument in opposition and therefore effectively concede that these opinions do not pass muster under *Daubert*. They should be excluded.

CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General Causation Testimony of Robert D. Moore, D.O., and limit his opinions for the reasons stated above and in its memorandum in support of its motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 27, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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